

**Notice of Allowability**

Application No.

10/580,528

Examiner

Nissa M. Westerberg

Applicant(s)

DANTANARAYANA ET AL.

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**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the Response to Election/Restriction filed 6/30/2008.
2. ☒ The allowed claim(s) is/are 1- 4.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- \* Certified copies not received: \_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date 6/30/2008
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413),  
Paper No./Mail Date 20080908.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_.

### EXAMINER'S AMENDMENT

1. Applicant's election of group I, claims 1 – 4 drawn to a method of treating glaucoma by the administration of a compound according to formula A, and the species of formula A recited in claim 4 in the reply filed on June 30, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election **without** traverse (MPEP § 818.03(a)).

As the elected species was not found, the search was expanded to the full scope of claim 1. The subject matter of claims 1 – 4, as amended below, is allowable.

As Applicants elected group I, drawn to methods, and not the compounds of group II, this application is not eligible for rejoinder.

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Patrick Ryan on September 5, 2008.

The application has been amended as follows:

#### **IN THE CLAIMS:**

In claim 1, replace line 11 of text through line 21 of text with the following text:

$R^7$  is chosen from

$C=OR^9$ ;

$S(O)_mR^{10}$ ;

$NR^{11}(C=O)R^{11}$ ;

$C_{1-6}$ alkyl substituted with hydroxyl,  $C_{1-6}$ alkoxy,  $OC(=O)C_{1-6}$ ,  $CO_2H$ ,  $CO_2C_{1-6}$ alkyl,  $C(=O)NR^{12}R^{13}$ ,  $S(O)_mNR^{12}R^{13}$ ,  $NR^{14}R^{15}$ , phenyl or a saturated or unsaturated 5 or 6-membered heterocyclic ring which can contain 1-4 heteroatoms selected from N, O, or S and can be unsubstituted or substituted with  $C_{1-6}$ alkyl,  $C_{1-6}$ alkoxy, halogen, halo $C_{1-6}$ alkyl, phenyl or pyridinyl; or

$R^7$  can be chosen from a heterocyclic ring selected from an oxazole such as oxazol-2-yl; 4,5-dihydro-oxazol-2-yl; or benzoxazol-2-yl; an oxazine such as 5,6-dihydro-[1,3]oxazin-2-yl; a thiazole such as thiazol-2-yl; 4,5-dihydro-thiazol-2-yl; or benzothiazol-2-yl; an imidazole such as imidazol-2-yl; or imidazolidin-2-yl; [1,2,4]oxadiazol-5-yl; [1,2,4]oxadiazol-3-yl;

[1,2,4]thiadiazol-5-yl; or [1,2,4]thiadiazol-3-yl, each of which can be unsubstituted or substituted with  $C_{1-6}$ alkyl,  $C_{1-6}$ alkoxy, phenyl, or pyridinyl, or  $C_{1-6}$ alkyl substituted with phenyl or pyridinyl;

In claim 2, please line 8 through line 18 with the following text:

$R^7$  is chosen from

$C=OR^9$ ;

$C_{1-6}$ alkyl substituted with hydroxyl,  $C_{1-6}$ alkoxy,  $OC(=O)C_{1-8}$ ,  $CO_2H$ ,  $CO_2C_{1-6}$ alkyl,  $C(=O)NR^{12}R^{13}$ ,  $S(O)_mNR^{12}R^{13}$ ,  $NR^{14}R^{15}$ , phenyl or a saturated or unsaturated 5 or 6-membered heterocyclic ring which can contain 1-4 heteroatoms selected from N, O, or S and can be unsubstituted or substituted with  $C_{1-6}$ alkyl,  $C_{1-6}$ alkoxy, halogen, halo $C_{1-6}$ alkyl, phenyl or pyridinyl; or

$R^7$  can be chosen from a heterocyclic ring selected from an ~~oxazole~~ such as oxazol-2-yl; 4,5-dihydro-oxazol-2-yl; or benzoxazol-2-yl; an ~~oxazine~~ such as 5,6-dihydro-[1,3]oxazin-2-yl; a ~~thiazole~~ such as thiazol-2-yl; 4,5-dihydro-thiazol-2-yl; or benzothiazol-2-yl; an ~~imidazole~~ such as imidazol-2-yl; or imidazolidin-2-yl; [1,2,4]oxadiazol-5-yl; [1,2,4]oxadiazol-3-yl; [1,2,4]thiadiazol-5-yl; or [1,2,4]thiadiazol-3-yl, each of which can be unsubstituted or substituted with  $C_{1-6}$ alkyl,  $C_{1-6}$ alkoxy, phenyl, or pyridinyl, or  $C_{1-6}$ alkyl substituted with phenyl or pyridinyl;

Claims 5 – 9 are cancelled.

3. The following is an examiner's statement of reasons for allowance: the claims of the instant application are drawn to a method of treating glaucoma or lowering or controlling intraocular pressure by administration of compounds according to formula A. Compounds with a similar core structure with a disclosed utility of 5-HT<sub>2C</sub> receptor antagonists are disclosed in US 6,245,796. '796 discloses that such compounds are useful for treating central nervous system disorders such as sexual disorders, anxiety, depression and sleeping disorders (col 1, ln 25 – 30). WO 01/70207 teaches that 5-HT<sub>2</sub>

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agonists that are taught as useful for treating central nervous system diseases (p 1 , In 30 – p 2, In 2) can also be used to lower and control intraocular pressure and to treat glaucoma (p 2, In 6 – 7). The compounds disclosed in table 3 of '796 (col 35 and 36) share a common core with the specific compounds disclosed in claims 3 and 4.

However, the possible values for  $R^7$  location of formula A of the instant application and those of the corresponding  $R^3$  and  $R^4$  substituents in the formula shown at the top of column 2 in '796 are mutually exclusive. One of ordinary skill in the art would not have any guidance or reason for selecting the  $R^7$  substituents as claimed in the instant application to produce compounds with 5- HT<sub>2C</sub> anatagonistic activity that are useful for the treatment of glaucoma or lowering or controlling intraocular pressure.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8:00 a.m. - 4 p.m. ET.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/  
Supervisory Patent Examiner, Art Unit 1618

NMW